



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/050,359 | 03/31/1998 | DANA M. FOWLKES | FOWLKES-4B | 6741 |

1444 7590 03/28/2005

BROWDY AND NEIMARK, P.L.L.C.
624 NINTH STREET, NW
SUITE 300
WASHINGTON, DC 20001-5303

EXAMINER

WESSENDORF, TERESA D

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1639

DATE MAILED: 03/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/050,359

Applicant(s)

FOWLKES ET AL.

Examiner

T. D. Wessendorf

Art Unit

1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 47-62 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 47-62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Status of Claims

Claims 47-62 are pending and under examination.

Withdrawn Objection and Rejection

The objection to the specification with respect to the used of the term structured is withdrawn in view of applicants' pointing out support at page 10, line 16. Also, the rejections under 35 USC 112, first paragraph (paragraph A); 35 USC 112, second paragraph and 35 USC 103 over Sparks are withdrawn in view of the new filed claims and applicants' arguments.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 101

Newly presented claims 47-62 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for reasons set forth in the last Office actions of in particular, 11/29/99 and 6/15/04.

Response to Arguments

Applicants argue that page 71 of the specification discloses a number of different phage libraries and submit that this constitutes a structure panel of peptides. It discloses ten separate libraries, each containing 5-amino acid and a constant amino acid. Ten different libraries each with a different fixed residue were produced and screened against UL44. The results are shown on pages 73-74 that show binding of two different libraries to UL44 and GSTUL44. Applicants submit that this shows that a panel of different biased combinatorial linear peptide libraries has been used to identify previously unknown target binding peptides and show evidence of utility. Applicants further submit that the Example on page 71 shows a structured panel i.e., a panel where there is some structural relationship between the member libraries, with a constant residue being at the same position. Applicants furthermore argue that at page 9, last paragraph, the specification defines a panel of combinatorial libraries as a collection of different, although possibly overlapping, and separately screenable simple or composite combinatorial libraries. A panel differs from the composite library in that the component simple libraries have not been mixed together (i.e., they may be screened separately).

In reply, screening of libraries per se is not screening of a panel. The claims are drawn to a panel hence, screening, if indeed, this is the only utility must be done to the compounds being claimed i.e., panel as a unit entity. This is analogous to saying that a peptide sequence comprised of individual amino acid residues has utility based on the utility of the individual amino acids. A panel is not combinatorial library. It is a much more complex composite of structured libraries. The reaction in a panel library is perhaps more complex and unpredictable relative to a single combinatorial library. (See page 74, lines 5-14 of the instant specification.) A panel, as stated above, is a collection of different and separately composite combinatorial library related in **some structural relationship** between member libraries. If the libraries are related only in some structural relationship between members, then what is the specific utility of a panel, as a unit? There is nothing in the specification that describes that the effect for the single tested and described library would all be the same for the other libraries in the panel that equates to the utility of a panel. To let applicants engross on yet undefined utility of the panel containing millions of also undefined and different libraries of compounds, would bar those who have actually discovered a real world utility for a panel of the type as claimed. Thus, the

Art Unit: 1639

prophetic statements in the specification regarding the utility of the library not a panel comprising these different libraries, lacks a specific and real world utility, as required by the statute.

Claims 47-62 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantial or specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

See the rejection and arguments above.

Claim Rejections - 35 USC § 112, first paragraph

Claims 47-62 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons set forth in the last Office actions of in particular, 11/29/99 and 6/15/04.

Response to Arguments

B). Applicants argue that the disclosure provides support for subpanel of a panel with more than two biased residue

Art Unit: 1639

positions. It is argued that page 10, lines 9-32 of the specification discloses that one may have structured panel of libraries in which one may define subpanels too.

In reply, the rejection is based on lack of written description for said subpanel, not new matter. The single remark at page 10, is not a specific description, as required by law. This cannot even be considered a definition of subpanel of a panel as recited. Since there is no specific panel description in the specification, it is little wonder, that a subpanel could not have a corresponding specific description. The law is clear that for an adequate written description of an invention involving a chemical genus, like a description of a chemical species, a precise definition, such as by structure, formula [or] chemical name of the claimed subject matter sufficient to distinguish it from other materials is essential. *University of California v. Eli Lilly and Co.*, 43 USPQ 2d 1398, 1405 (1997), quoting *Fiers v. Revel*, 25 USPQ 2d 1601m 16106 (Fed. Cir. 1993).

The claim recites only a generic formula for a library comprised in a panel or a subpanel comprised in a panel. There are just too numerous undefined variables for each of the components in a panel e.g., library and its members, viruses or cells and other undefined claimed variables. The specification

Art Unit: 1639

has not sufficiently shown that at the time of filing, applicants are in possession of the claimed genus.

C). The new matter rejections of then amended claims, and as applied to new claims 47-62 are reiterated below:

1. Claim 47, for example, "a plurality of biased combinatorial linear peptide libraries". Cf. with the definition of "structured panel" at page 10, line 1 of the specification. The specification does not define a plurality or the maximum number encompassed by said plurality; "in which the peptides are displayed on viruses" and "each library being a separate and physically distinct entity."

Response to Arguments

Applicants argue that page 9, lines 9-12 provide support for the claimed plurality of biased combinatorial linear peptide libraries. It defines a biased combinatorial library as one in which at one or more position in the library member only one of the possible biased elements is allowed for all member of the library i.e., the biased positions are invariant. The examiner's attention has been drawn to page 10, lines 1-8 which defines "structure panel" as a panel where there is some structural relationship between the member libraries."

In response, the definitions at page 9 and of a panel are not a clear support for the claimed " plurality of biased

Art Unit: 1639

combinatorial linear peptide libraries." The plurality has not been defined in the specification i.e., there is no lower or upper limit for said plurality. (It suggested that applicants' recite terms in the claims consistent with that of the disclosure).

Applicants have not responded to the above rejection of "peptides are displayed on viruses" and "each library being a separate and physically distinct entity." Since applicants have not responded to this rejection, it is believed that applicants are acquiescing therewith.

2. The entire claims 32-35, 39, and 43-46 (now claims 57, 59, 61, 52, 58, 60 and 62, respectively). For example, the proviso "where if said libraries comprise more than two constant residue positions, the constant residue positions other than said first and second positions are constant for all peptides in said panel." In claim 32 (now claim 57), for example, "where said panel comprises a plurality of subpanel." In claim 33 (now claim 59), for example, the claim to a "subset of a set", especially as applied in the context of the claimed structured panel.

Response to Arguments

Applicants argue that the specification at page 27, lines 25-38 and pages 28 and 29 provide support for the claimed

proviso "where if said libraries comprise more than two constant residue positions, the constant residue positions other than said first and second positions are constant for all peptides in said panel." Additional support is said to be found in the initially filed claims. Applicants further submit that support for the term "subpanel" as used in the claims can be found on at page 10, lines 16 which states that "one may have structured panels of libraries in which one may define subpanels, too." For example, in one subpanel, the middle residue AA1 may be the same for all libraries, but the libraries also have a constant AA2 which is scanned through all other residue portions." Applicants also submit-that-one-skilled-in-the-art would understand, from reading the disclosure as a whole, the meaning of the term subpanel. Applicants further submit that support for the claimed "subset of a set" is in the originally filed claims.

In response, pages 27-29 and the as-filed claims do not provide clear support for holding more than two constant residue positions. Rather, it discloses only two constant residue positions. The holding of the two constant residues is disclosed relative to the given structure therein, not as to the broadly claimed panel. Page 10, line 16, as recited above, supports subpanel not a plurality of subpanel as claimed. Whether a term

Art Unit: 1639

constitutes new matter is not whether a skilled artisan would understand its meaning, rather, whether the term is originally present in the as-filed specification. There is nothing in the originally filed claims that recite for a "subset of a set."

Newly presented claims 47-62 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for reasons stated in the last office action of 6/15/04.

Response to Arguments

Applicants argue that the method of making and using a structured panel is described at pages 25-37 and Example 1. It is argued to describe the preparation and use of peptide libraries. One skilled in the art understands that the preparation and use of libraries comports with the preparation and use of the instant claimed structured panel.

In reply, throughout the specification and as acknowledge by applicants above, only libraries have been made with its alleged use. The examples in the specification provide prophetic statements for a panel of library. There is no mention of a method of making and using a panel except for the prophetic

Art Unit: 1639

statements made for the library. It vaguely and broadly defines a panel as some structural relationship between the member libraries. Just how or what exactly the some structural relationship between the member libraries cannot be envisaged from the general description. There is no description as to how the preparation and use of a single library comports with the preparation and use of the instant claimed structured unit, panel. Thus, the specification, at the time of filing, has not taught how to make and use a panel as required by the law.

Claim Rejections - 35 USC § 103

New claims 47-62 are rejected under 35 under 35 U.S.C. 103(a) as being obvious Cantley et al (USP 5,532,167) in view of Pinilla (USP 5,556,762) for reasons advanced in the last Office action, 6/15/04.

Response to Arguments

Applicants argue that Pinilla does not disclose or suggest an amino acid at a second fixed position.

In response, attention is directed to col. 11, lines 10-20 of the Pinilla reference.

Applicants agree that Cantley discloses a polypeptide library that has a constant, fixed amino acid. But disagree that Cantley discloses a structured panel consists of panels of

Art Unit: 1639

libraries. Cantley is argued to disclose amino acid selected from Ser, Thr and Tyr. That there are a number of variable amino acid on each side of this fixed amino acid specifically one and ten amino acids in each side. It is further argued that the Cantley reference does not disclose a plurality of biased combinatorial library.

In response, the tyrosine taught by Cantley is included in the claimed fixed residues as recited in claim 56 having no defined number of variable residues for XX. Therefore, 10-residue taught by Cantley would read on the XX numbers of variables. Furthermore, attention is directed to Cantley at col. 3, line 1 up to col. 12, line 1 which disclose a degenerate peptide library (i.e., a biased library) which is a population of peptides in which different amino acid residues are present at the same position in different peptides within the library. For example, a population of peptides of 10 amino acids in length in which the amino acid residue at position 5 of the peptides can be any one of the twenty amino acids would be a degenerate peptide library. As applicants state at page 17 of the instant REMARKS "one skilled in the art would understand that the explanation and preparation and use of libraries...comports with the preparation...of ...structural panel." See further applicants' previous REMARKS stating the equivalency of

Art Unit: 1639

Pinilla's panel to the instant panel. Accordingly, the combined teachings of the references render the claimed structured panel prima facie obvious to one having ordinary skill in the art.

No claim is allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

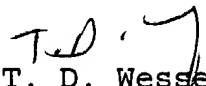
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (571)272-0812. The examiner can normally be reached on Flexitime.

Art Unit: 1639

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571)272-081. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


T. D. Wessendorf
Primary Examiner
Art Unit 1639

Tdw

March 21, 2005